

Validation of the Spanish Version of the Food Allergy Quality of Life Questionnaire-Parent Form (S-FAQLQ-PF)

RUNNING TITLE: QUALITY OF LIFE QUESTIONNAIRE VALIDATION

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VALIDATION OF THE SPANISH VERSION OF THE FOOD ALLERGY QUALITY OF LIFE QUESTIONNAIRE-PARENT FORM (S-FAQLQ-PF)

ABSTRACT:

Background: Food allergy is an emerging health problem in the last years. There are many different questionnaires that could be used to establish health related quality of life in food allergy patients. It is important to perform lingual and cultural translations of existent questionnaires.

Objective: To perform lingual and cultural translation and cross-sectional validation of the Food Allergy Quality of Life Questionnaire-Parent Form (FAQLQ-PF).

Methods: Parents of 54 subjects previously diagnosed of food allergy were recruited to perform lingual and cultural translation into Spanish of the FAQLQ-PF.

Results: Translation to Spanish of the S-FQLQ-PF according to the WHO guidelines (including a forward-backward translation) was performed. Statistical analysis showed that feasibility, reliability and internal consistency presented very good results for global S-FAQLQ-PF score and for the different domains. Construct validity was assessed and results suggest that S-FAQLQ-PF has lower capability to measure HRQL in younger children. Finally, cross-sectional validation of the S-FAQLQ-PF demonstrate that patients' age, severity of symptoms or number of reactions affect the HRQL of a pediatric Spanish population, whereas sex, food implicated, number of implicated foods, transgression with the implicated food as well as presence of anaphylaxis don't affect HRQL.

Conclusion: We report the lingual and cultural translation of the specific food allergy HRQL questionnaire - FAQLQ-PF - into Spanish language, and it has been used to demonstrate the influence of different factors, such as patients' age, severity of symptoms or number of reactions, in the HRQL of a pediatric Spanish population.

KEY WORDS: Allergy. Food allergy. Quality of life. Questionnaire. Spanish. Validation.

RESUMEN:

Introducción: La alergia a alimentos se ha convertido en un problema de salud en aumento en los últimos años. Existen múltiples cuestionarios que sirven para establecer el nivel de calidad de vida en los pacientes alérgicos a alimentos. Es importante realizar adaptaciones lingüísticas y culturales de los cuestionarios existentes a todos los idiomas.

Objetivo: Realizar una adaptación lingüística y cultural al español así como una validación transversal del cuestionario Food Allergy Quality of Life Questionnaire-Parent Form (FAQLQ-PF).

Métodos: Los padres de 54 pacientes diagnosticados de alergia a alimentos fueron reclutados para llevar a cabo la adaptación lingüística y cultural al español del cuestionario FAQLQ-PF.

Resultados: Se realizó la traducción al español del cuestionario FAQLQ-PF (S-FAQLQ-PF) de acuerdo a las guías de la OMS. El análisis estadístico demostró que la viabilidad, fiabilidad y la consistencia interna era buena tanto para los resultados globales del S-FAQLQ-PF como para los diferentes dominios del mismo. La validez de constructo fue evaluada y los resultados sugieren que el S-FAQLQ-PF presenta peor capacidad para medir la calidad de vida en los niños de menor edad (0-3 años). Finalmente, la validación transversal del S-FAQLQ-PF ha demostrado que la edad de los pacientes, la gravedad de los síntomas o el número de reacciones sufridas afectan a la calidad de vida en una población pediátrica española, mientras que el género, el tipo o el número de alimentos, la presencia de anafilaxia y las transgresiones dietéticas no la afectan.

Conclusiones: Presentamos la adaptación lingüística y cultural al español del cuestionario de vida específico para alergia a alimentos S-FAQLQ-PF. Esta adaptación se ha utilizado para demostrar la influencia de diferentes factores, como la edad de los pacientes, la gravedad de los síntomas o el número de reacciones sufridas en la calidad de vida de una población pediátrica española.

PALABRAS CLAVE: Alergia. Alergia a alimentos. Calidad de vida. Cuestionario. Español. Validación.

VALIDATION OF THE SPANISH VERSION OF THE FOOD ALLERGY QUALITY OF LIFE QUESTIONNAIRE-PARENT FORM (S-FAQLQ-PF)

INTRODUCTION:

Food allergy is an emerging health problem in the last few years, with an alarming increase in prevalence, especially when it is referred to children population in developed countries [1]. Food allergy is characterized by different clinical features, including cutaneous, respiratory and gastrointestinal symptoms; some of them are even able to provoke a fatal reaction [2]. Due to these characteristics, food allergy affects health-related quality of life (HRQL) not only in patients, but also in their families and caregivers [3, 4].

HRQL may be the only significant outcome measure available for food allergy, measuring this continuous burden, and for this reason specific questionnaires have been developed in the last years. These questionnaires should be short and easy to complete to become a useful tool in the clinical practice. There are many different questionnaires that could be used to establish the HRQL in these patients. HRQL has been demonstrated to differ depending on the age of the patient, so it is important to develop specific questionnaires for every age. Specific questionnaires for children have been developed in the last years, most of them should be completed by their parents [5, 6], but some of them shall be answered by the children [7, 8]. Probably within Europe, the Food Allergy Quality of Life Questionnaires (FAQLQ) are the most used questionnaires in children, which were developed and validated in Europe as a part of EuroPrevall Project. These questionnaires include versions for children from 0 to 18 years old and for their parents [5, 7, 8]. It is important to perform lingual and cultural translations of existent questionnaires into different languages [9, 10] to apply them in different countries with distinct socio-economic realities.

Therefore, the aim of this study was to perform lingual and cultural translation and cross-sectional validation of the first disease-specific HRQL questionnaire for children with food allergy in Spanish, namely the Food Allergy Quality of Life Questionnaire-Parent Form (FAQLQ-PF).

METHODS

Questionnaires

Two different questionnaires were used to perform lingual and cultural translation into Spanish, first of all, the aforementioned Food Allergy Quality of Life Questionnaire-Parent Form translated to Spanish (S-FAQLQ-PF), and secondly, the Spanish version of the Food Allergy Independent Measure (FAIM).

FAQLQ-PF was translated to Spanish according to the WHO guidelines [11] that recommend translation based on a forward-backward method (Supplementary Table 1). Briefly, this kind of translation includes: 1) English to Spanish translation (Forward translation), 2) Review by expert panel, 3) Backward translation to English of the Spanish version by a native speaker, 4) Pre-testing and cognitive interviewing in collaboration with the Spanish Food and Latex Allergy Patients Association (AEPNAA), and 5) Final version.

FAQLQ-PF questionnaire includes 3 different domains that warrant assessment of the impact of food allergy in HRQL. These domains are emotional impact (EI), food anxiety (FA) and, social and dietary limitation (SDL). EI is related to psychological experiences, FA is related to fear and apprehension about food and, finally, SDL concerns everyday dietary and social restrictions [12].

Participant subjects

Parents of 54 subjects between 0 and 12 years (median 50.5 months or 4.21 years) were recruited at the allergy outpatient clinic, at a tertiary hospital from Madrid, Spain (Hospital Universitario del Sureste, Arganda del Rey, Spain). The questionnaire package was handed out to 66 Spanish child-parent pairs and returned by 54 child-parent pairs (response rate 81.82%). All of them should be previously diagnosed of food allergy and fulfilling these inclusion criteria: 1) presence of immediate allergic symptoms after the ingestion of any food and positive cutaneous test or elevated IgE levels to these foods, and 2) capacity to understand and answer properly all the questionnaires. The exclusion criteria were: 1) parents were unable to complete the questionnaire, and 2) presence of another major illness which could impair HRQL (either atopic or non-atopic).

Patients were classified in 3 different groups of age: 0-3 years-old (22 subjects), 4-6 years-old (15 subjects) and 7-12 years-old (13 subjects). Clinical and epidemiological characteristics of

these patients were also collected and are summarized in Table 1. Patients' parents (43 mothers and 11 fathers) completed the S-FAQLQ-PF, a Spanish language specific HRQL questionnaire (FAIM scale) as well as a Spanish language generic HRQL questionnaire (Kindl Questionnaire [13, 14]). Parents repeated the test at home, with an altered order of questions up to 10-14 days after the first completed version. Second questionnaire was sent back to our hospital by ordinary mail. Time employed and need of help to answer the questionnaires was also documented.

Ethical disclosure

The study was approved by the University Hospital Gregorio Marañón Ethics Committee on September 30th 2013 (Acta 11/2013) and involved a full written parental consent. Parents and children received written information, indicating that participation in the study was voluntary.

Statistical analysis

Most important statistical concepts were calculated (Supplementary Table 2) with the data obtained from the patients. The raw S-FAQLQ-PF and FAIM scores 0 to 6 were recoded as 1 to 7 to facilitate statistical analyses. The statistical package used for all the analysis was Stata 14.1 for Windows (Stata Corp. 2015. Stata Statistical Software: Release 14. College Station, TX: Stata Corp LP).

Feasibility and Reliability

Questionnaire feasibility was measured as the percentage of S-FAQLQ-PF fully completed.

It was also evaluated the test-retest reliability by comparing the original S-FAQLQ-PF and a second version containing the same items in an altered order about 10 to 14 days later. Reliability has been calculated using interclass correlation coefficient (ICC).

Internal consistency and floor/ceiling effect

Cronbach's α has been used to assess internal consistency of the S-FAQLQ-PF. Internal consistency evaluates if all the items included in the questionnaire that are trying to measure the same bring similar results.

Floor/Ceiling effect refers to the percentage of subjects that score the lowest/highest punctuation in the questionnaire. High percentage of subjects indicates that the questionnaire is not able to evaluate differences between patients. Criteria for acceptability included <15% floor and ceiling effects for global score and different domains [16].

Construct validity

Construct validity has been analyzed through comparison of the S-FAQLQ-PF results and the results of a validated HRQL questionnaire (FAIM scale in this occasion). Spearman's Correlation Coefficient of both questionnaires was compared to establish construct validity of S-FAQLQ-PF. Comparison with a generic HRQL (Kindl questionnaire [17]) was also performed to confirm construct validity results.

Discriminant validity

Mann-Whitney U and Kruskal Wallis tests were performed to assess influence of the epidemiological and clinical characteristics of the included subjects for global S-FAQLQ-PF score and for all the different domains, to evaluate the discriminant validity of this questionnaire. Differences between sex, age, presence or absence of anaphylaxis (recorded in the clinical history of the patient), transgressions with the implicated food, related symptoms, number of reactions and the number of foods implicated were evaluated.

RESULTS

Feasibility and Reliability

Questionnaires' feasibility has been evaluated in 54 questionnaires. 52 questionnaires (96.3%) were totally completed, whereas 2 questionnaires (3.7%) were not totally completed. In those that were not totally completed, one of them was almost completed (just one item was not filled) meanwhile in the second one only one item was filled because parents referred that the rest of the items were not applicable for a child younger than 3 years. Less than a quarter of the parents (11 of them) needed assistance in completing the questionnaire.

A total of 50 subjects fully completed both S-FAQLQ-PF (first of them in the visit they were included in the study, and the second one, including the items in an altered order, about 10 to 14 days later). Reliability was calculated for the 3 different groups of age: 0-3 years-old (22 subjects, because of the patient that only filled one item), 4-6 years-old (15 subjects) and 7-12 years-old (13 subjects), and for the different domains of the S-FAQLQ-PF including: emotional impact (EI), food anxiety (FA) and, social and dietary limitation (SDL). ICC for the different groups of age varied from 0.898 to 0.973 and ICC for different domains showed a value higher than 0.75 in all the groups of age (data are shown in Table 2).

Internal consistency and floor/ceiling effect

A questionnaire is considered to have a good internal consistency when Cronbach's α presents a value higher than 0.8. In our study all the results were higher than 0.8 both for different groups of age (0.897 to 0.90) and the different domains (0.809 to 0.946).

As regards floor/ceiling effect, none of the questionnaires presented the higher possible punctuation (ceiling effect). On the other hand, 3 subjects belonging to the 0-3 year-old group (5.5% of the total of the patients) completed the questionnaire with the lowest punctuation (floor effect). All these data are summarized in Table 2.

Construct validity

A significant correlation was observed between S-FAQLQ-PF and FAIM scale in the groups of 4-6 and 7-12 year-old for global S-FAQLQ-PF score and for all the different domains (Supplementary Table 3), except for the SDL domain in the 7-12 year-old group. In the other group (0-3 year-old group), only the EI and the SDL domains presented a significant correlation with the mean score of FAIM scale.

Moreover, with regards to the comparison between S-FAQLQ-PF and Kindl Questionnaires (Kiddy Kindl for children 4-6 year-old and Kid Kindl for children 7-12 year-old), there was a statistically significant correlation exclusively between the S-FAQLQ-PF EI domain and the Kiddy-Kindl Family domain (data not shown).

Discriminant validity (Table 3)

First of all, Mann-Whitney U test obtained no differences between sex groups. Statistical significance was observed for the 7-12 years-old group in the global S-FAQLQ-PF score and for EI and FA domains, and for the 4-6 years-old group in the EI and FA domains (it was close to statistical significance in the global S-FAQLQ-PF score) when different age groups were compared. Parents of 0-3 year-old group reported lower punctuation, better HRQL, in the global S-FAQLQ-PF score than 4-6 and 7-12 year-old groups (no statistical significant differences were observed between these last two groups). Parents of 4-6 and 7-12 year-old groups reported higher medium punctuation for EI [difference of 1.0 ($p = 0.001$) and 1.3 ($p < 0.001$) respectively] and for FA [difference of 1.1 ($p = 0.027$) and 1.4 ($p = 0.002$) respectively]. It was also evaluated difference regarding number of reactions that the patients had suffered. In this term analysis showed that patients with a lower number of reactions (1-4 reactions) presented better HRQL than those that suffered 5 or more reactions [in the global S-FAQLQ-PF

score ($p = 0.004$) and for all the different domains: EI $p = 0.011$, FA $p = 0.004$, SDL $p = 0.019$]. When the Kruskal-Wallis test was used to evaluate differences according to patients' symptoms, it was observed that patients with respiratory and gastrointestinal symptoms presented worst HRQL for the global S-FAQLQ-PF score ($p = 0.011$ and $p = 0.060$ respectively), and that patients who presented anaphylaxis had a worst result for the global S-FAQLQ-PF score and for all the domains, but no statistical significance was observed.

No differences were observed between patients when presence or absence of anaphylaxis, transgression with the implicated food or the number of foods implicated, were analyzed. Neither was observed any difference in the global S-FAQLQ-PF when the foods implicated were analyzed.

DISCUSSION

Measuring HRQL is an important way to evaluate the repercussion and the impact of an illness in patients. It has been demonstrated that it is also important in food allergy patients [3, 18, 19]. Cultural, culinary and socio-economical differences may influence the ability of the questionnaires to identify essential items for pediatric food-allergic patients in Spanish-speaking population. This study aimed to obtain a lingual and culturally equivalent version of the FAQLQ-PF in Spanish language and to demonstrate that it is useful in a Spanish pediatric population, to serve as a suitable tool to evaluate the HRQL.

Translation to Spanish according to the WHO guidelines (including a forward-backward translation) was performed as a first step [11]. Parents of 54 food allergy diagnosed children between 0 and 12 years completed the S-FAQLQ-PF, in a first time and 10 to 14 days afterwards, FAIM scale and a generic quality of life questionnaire (Kindl Questionnaire). Finally, clinical and epidemiological characteristics and results of the questionnaires were analyzed and evaluated. A remarkable strength of our study is that clinical symptoms of anaphylaxis and indication of epinephrine were obtained from clinical history reports, not from patient reports.

When we refer to statistical analysis in our study, it is important to remark that feasibility, reliability and internal consistency presented very good results for global S-FAQLQ-PF score and for the different domains. All these results support that S-FAQLQ-PF is a really good tool to measure HRQL, and that it could be used in the Spanish population (between 0 to 12 years of age). Measuring of the floor/ceiling effect revealed that a small percentage of subjects (5.5% of the total of the patients) completed the questionnaire with the lowest punctuation, all

these subjects belonged to the 0-3 year-old group, and it is probably related with the small amount of items that they should complete.

Finally, construct validity was assessed comparing S-FAQLQ-PF results with a specific HRQL questionnaire (FAIM scale) and a generic HRQL questionnaire (Kindl Questionnaire). Results obtained when compared with FAIM scale were statistically significant for the 4-6 year-old and 7-12 year-old groups (except for the SDL domain in the 7-12 year-old group), but not for the 0-3 year-old group, where only the EI and the SDL domain were statistically significant. These results may imply that the S-FAQLQ-PF has lower capability to measure HRQL in younger children. These data reinforced the idea that specific HRQL questionnaires should be performed to improve its quality, and it could be a good point of beginning for a next study in younger children. Regarding comparison between S-FAQLQ-PF and the generic Kindl Questionnaires no correlation was observed, except for S-FAQLQ-PF EI domain and Kiddy-Kindl Family domain. It has been demonstrated that generic HRQL questionnaires are not valid to measure the effect of food allergy in HRQL, because these kind of questionnaires are focused in the diary or frequent fluctuations in physical status of the patients, whereas food allergy causes severe symptoms in punctual moments, but not in a day-to-day basis [20, 21].

Cross-sectional validation of the S-FAQLQ-PF generates important information about HRQL in our population. First of all, no differences were observed when comparing sex, food implicated, number of implicated foods or transgression with the implicated food of participants. Relationship between all these factors should be reviewed because inconsistent results have been observed in different studies [22]. Presence of anaphylaxis didn't influence in HRQL, although the number of patients that presented it is low when compared with those that don't have presented anaphylaxis, something that could bias these results [23]. Regarding population age, patients belonging to 0-3 years-old group presented better HRQL than older patients, as it has been described in a Swiss population [24]. It has been observed that patients who presented more severe symptoms (gastrointestinal, respiratory or multisystemic symptoms) have a lower HRQL, than those who presented cutaneous symptoms [20, 22]. Finally, the relationship between HRQL and number of reactions presented by the patients was also evaluated. Patients which have presented 5 or more reactions with foods refer worst values than those with 4 or less reactions, it has been also observed in other studies [25].

In summary, we report the lingual and cultural translation of the specific food allergy HRQL questionnaire - FAQLQ-PF - into Spanish language. Moreover, initial cross-sectional validation of this questionnaire was performed. The S-FAQLQ-PF presents similar results than those

obtained in the original version, and it has been used to demonstrate the influence of different factors, such as patients' age, severity of symptoms or number of reactions, in the HRQL of a pediatric Spanish population. We have found a lack of utility of the S-FAQLQ-PF in patients 0 to 3 years-old, and it suggests that new specific questionnaires for this age should be performed in the future.

This questionnaire is an interesting tool to evaluate HRQL in the Spanish food allergic population and, even, could be used in all the Spanish-speaking food allergic population (about 500 million people in the last years) until specific questionnaires for each Spanish-speaking country are created, as well as to evaluate influence of food avoidance, oral provocation challenges [5] or new treatments such as food immunotherapy [26, 27], in patients' HRQL. S-FAQLQ-PF has been adapted not only to Spanish language but also to our population culture, expectations and socio-economic characteristics.

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REFERENCES

1. Sicherer SH, Sampson HA. Food allergy: Epidemiology, pathogenesis, diagnosis, and treatment. *J Allergy Clin Immunol* 2014;133:291-307.
2. Worm M, Grünhagen J, Dölle S. Food-induced anaphylaxis - data from the anaphylaxis registry. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* 2016;59:836-40.
3. Warren CM, Otto AK, Walkner MM, Gupta RS. Quality of Life Among Food Allergic Patients and Their Caregivers. *Curr Allergy Asthma Rep* 2016;16:38.
4. Franxman TJ, Howe L, Teich E, Greenhawt MJ. Oral food challenge and food allergy quality of life in caregivers of children with food allergy. *J Allergy Clin Immunol Pract* 2015;3:50-6.
5. DunnGalvin A, Cullinane C, Daly DA, Flokstra-de Blok BM, Dubois AE, Hourihane JO. Longitudinal validity and responsiveness of the Food Allergy Quality of Life Questionnaire - Parent Form in children 0-12 years following positive and negative food challenges. *Clin Exp Allergy* 2010;40:476-85.
6. Knibb RC, Barnes C, Stalker C. Parental confidence in managing food allergy: development and validation of the Food Allergy Self-Efficacy Scale for Parents (FASE-P). *Clin Exp Allergy* 2015;45:1681-9.
7. Flokstra-de Blok BM, DunnGalvin A, Vlieg-Boerstra BJ, Oude Elberink JN, Duiverman EJ, Hourihane JO, et al. Development and validation of a self-administered Food Allergy Quality of Life Questionnaire for children. *Clin Exp Allergy* 2009;39:127-37.
8. Flokstra-de Blok BM, DunnGalvin A, Vlieg-Boerstra BJ, Oude Elberink JN, Duiverman EJ, Hourihane JO, et al. Development and validation of the self-administered Food Allergy Quality of Life Questionnaire for adolescents. *J Allergy Clin Immunol* 2008;122:139-44,144.e1-2.
9. Antolin-Amerigo D, CerecedoCarballo I, Muriel A, Fernández-Rivas M, Diéguez Pastor M, Flokstra-de Blok B, et al. Validation of the Spanish Version of the Food Allergy Quality of Life Questionnaire-Adult Form (S-FAQLQ-AF). *J Investig Allergol Clin Immunol* 2015;25:270-5.
10. Couto M, Silva D, Piedade S, Borrego L, Flokstra-de Blok B, Dunn Galvin A, et al. Translation to Portuguese and cultural adaptation of Food Allergy Quality of Life Questionnaire - Parent Form (FAQLQ-PF). *Eur Ann Allergy Clin Immunol* 2016;48:82-7.
11. World Health Organization. Process of translation and adaptation of instruments.http://www.who.int/substance_abuse/research_tools/translation/en/

12. DunnGalvin A, de BlokFlokstra BM, Burks AW, Dubois AE, Hourihane JO. DunnGalvin A, de BlokFlokstra BM, Burks AW, Dubois AE, Hourihane JO. *Clin Exp Allergy* 2008;38:977-86.
13. Ravens-Sieberer U, Bullinger M. Assessing health-related quality of life in chronically ill children with the German KINDL: first psychometric and content analytical results. *Qual Life Res* 1998;7:399-407.
14. Fernández-López JA, Fernández Fidalgo M, Cieza A, Ravens-Sieberer U. Measuring health-related quality of life in children and adolescents: preliminary validation and reliability of the Spanish version of the KINDL questionnaire. *Aten Primaria* 2004;33:434-42.
15. Antolín-Amérigo D, Manso L, Caminati M, de la Hoz Caballer B, Cerecedo I, Muriel A, et al. Quality of life in patients with food allergy. *Clin Mol Allergy* 2016;17;14:4.
16. Terwee CB, Bot SD, de Boer MR, van der Windt DA, Knol DL, Dekker J, et al. Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol* 2007;60:34–42.
17. Rajmil L, Serra-Sutton V, Fernandez-Lopez JA, Berra S, Aymerich M, Cieza A, et al. The Spanish version of the German health-related quality of life questionnaire for children and adolescents: the Kindl. *An Pediatr (Barc)* 2004;60:514-21.
18. Lieberman JA, Sicherer SH. Quality of life in food allergy. *Curr Opin Allergy Clin Immunol* 2011;11:236-42.
19. Morou Z, Tatsioni A, Dimoliatis ID, Papadopoulos NG. Health-related quality of life in children with food allergy and their parents: a systematic review of the literature. *J Investig Allergol Clin Immunol* 2014;24:382-95.
20. Greenhawt M. Food allergy quality of life and living with food allergy. *Curr Opin Allergy Clin Immunol* 2016;16:284-90.
21. Flokstra-de Blok BM, van der Velde JL, Vlieg-Boerstra BJ, Oude Elberink JN, DunnGalvin A, Hourihane JO, et al. Health-related quality of life of food allergic patients measured with generic and disease-specific questionnaires. *Allergy* 2010;65:1031-8.
22. Saleh-Langenberg J, Goossens NJ, Flokstra-de Blok BM, Kollen BJ, van der Meulen GN, Le TM, et al. Predictors of health-related quality of life of European food-allergic patients. *Allergy* 2015;70:616-24.
23. Protudjer JL, Jansson SA, Östblom E, Arnlinde MH, Bengtsson U, Dahlén SE, et al. Health-related quality of life in children with objectively diagnosed staple food allergy assessed with a disease-specific questionnaire. *Acta Paediatr* 2015;104:1047-54.

24. Wassenberg J, Cochard MM, Dunngalvin A, Ballabeni P, Flokstra-de Blok BM, Newman CJ, et al. Parent perceived quality of life is age-dependent in children with food allergy. *Pediatr Allergy Immunol* 2012;23:412-9.
25. Sicherer SH, Noone SA, Muñoz-Furlong A. The impact of childhood food allergy on quality of life. *Ann Allergy Asthma Immunol* 2001;87:461-4.
26. Factor JM, Mendelson L, Lee J, Nouman G, Lester MR. Effect of oral immunotherapy to peanut on food-specific quality of life. *Ann Allergy Asthma Immunol* 2012;109:348-352.e2.
27. Carraro S, Frigo AC, Perin M, Stefani S, Cardarelli C, Bozzetto S, et al. Impact of oral immunotherapy on quality of life in children with cow milk allergy: a pilot study. *Int J Immunopathol Pharmacol* 2012;25:793-8.

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Table 1. Patients' clinical and epidemiological characteristics

Variable	n (%)
Sex	
Male	36 (66.7)
Female	18 (33.3)
Age (months)*	
	50.5 (30 ; 96)
Age (Years)	
0 - 3	23 (42.6)
4 - 6	17 (31.5)
7 - 12	14 (25.9)
Anaphylaxis	
Yes	13 (24.0)
No	41 (76.0)
Food transgression (any time)	
Yes	21 (38.9)
No	33 (61.1)
Symptoms	
Cutaneous	32 (59.2)
Gastrointestinal	7 (13.0)
Respiratory	11 (20.4)
Multisystemic	4 (7.4)
Number of reactions	
1 - 4	47 (87.0)
5 +	7 (13.0)
Implicated foods	
Single	24 (44.4)
Multiple	30 (55.6)
Food**	
Egg	29 (53.7)
Nuts (including peanut)	19 (35.2)
Milk	15 (27.8)
Fish/shellfish	12 (22.2)
Fruits	3 (5.5)
Other	4 (7.4)

* Median (p25;p75)

** Percentage higher than 100% due to multiple allergies

Table 2. Reliability, internal consistency and floor/ceiling effect

S-FALQL-PF ^(*)	Group (Years)	n	Item	Mean (SD)	Cronbach's α	%min/%max (floor/ceiling)	ICC ^(**)
Global score	0 – 3	22	14	2.1 (1.0)	0.897	13.6/0	0.898
	4 – 6	17	26	2.8 (1.3)	0.960	0/0	0.902
	7 – 12	14	30	3.0 (1.1)	0.952	0/0	0.973
EI score ^(***)	0 – 3	22	6	1.6 (0.9)	0.882	40.9/0	0.772
	4 – 6	17	10	2.6 (1.0)	0.856	5.9/0	0.790
	7 – 12	14	13	2.9 (1.0)	0.896	0/0	0.928
FA score ^(***)	0 – 3	22	3	2.1 (1.3)	0.823	45.4/0	0.799
	4 – 6	17	7	3.2 (1.7)	0.946	11.7/0	0.932
	7 – 12	14	8	3.4 (1.5)	0.895	0/0	0.957
SDL score ^(***)	0 – 3	22	5	2.6 (1.4)	0.809	13.6/0	0.822
	4 – 6	17	9	2.7 (1.5)	0.916	5.9/0	0.859
	7 – 12	14	9	2.6 (1.2)	0.830	14.3/0	0.954

^(*) S-FAQLQ-PF: Spanish Food Allergy Quality of Life Questionnaire – Parent Form.

^(**) Interclass correlation coefficient

^(***) EI: Emotional impact; FA: Food anxiety; SDL: Social and dietary limitation.

Table 3. Discriminant validity

Variable		n	Global S-FAQLQ score		EI	FA		SDL		
Sex	Male	35	2.6 (1.2)	0.977	2.3 (1.1)	0.792	2.8 (1.6)	0.940	2.7 (1.4)	0.763
	Female	18	2.6 (1.2)		2.3 (1.1)		2.8 (1.6)		2.6 (1.4)	
Age (years)	0 – 3 (ref.)	22	2.1 (1.0)		1.6 (0.9)		2.1 (1.3)		2.6 (1.4)	
	4 – 6	17	2.8 (1.3)	0.074	2.6 (1.0)	0.001*	3.2 (1.7)	0.027*	2.7 (1.5)	0.921
	7 – 12	14	3.0 (1.1)	0.008*	2.9 (1.0)	< 0.001*	3.5 (1.4)	0.002*	2.6 (1.4)	0.820
Anaphylaxis	Yes	13	2.8 (1.2)	0.301	2.6 (0.8)	0.108	3.1 (1.5)	0.367	2.8 (1.7)	0.877
	No	40	2.5 (1.2)		2.2 (1.2)		2.7 (1.6)		2.6 (1.3)	
Transgression	Yes	21	2.9 (1.3)	0.161	2.5 (1.0)	0.127	3.1 (1.6)	0.323	3.0 (1.4)	0.321
	No	32	2.4 (1.2)		2.2 (1.1)		2.6 (1.6)		2.4 (1.1)	
Symptoms	Cutaneous (ref.)	31	2.2 (1.1)		2.0 (1.1)		2.3 (1.5)		2.3 (1.1)	
	Gastrointestinal	7	3.2 (1.0)	0.060	2.6 (0.9)	0.107	3.9 (1.7)	0.030*	3.0 (1.0)	0.079
	Respiratory	11	3.2 (1.2)	0.011*	3.0 (1.0)	0.003*	3.5 (1.4)	0.021*	3.0 (1.7)	0.213
	Multisystemic	4	3.1 (1.6)	0.276	2.5 (1.3)	0.359	2.9 (1.7)	0.461	3.9 (2.0)	0.113
Number of reactions	1 – 4	46	2.4 (1.1)	0.004*	2.1 (1.0)	0.011*	2.6 (1.5)	0.004*	2.5 (1.3)	0.019*
	5 +	7	3.9 (1.1)		3.4 (0.9)		4.5 (1.2)		3.9 (1.5)	
Implicated foods	Single	23	2.3 (1.1)	0.146	2.2 (1.1)	0.372	2.6 (1.6)	0.279	2.2 (1.0)	0.074
	Multiple	30	2.8 (1.3)		2.4 (1.1)		3.0 (1.6)		3.0 (1.4)	
Egg/Milk allergy	Yes	33	2.5 (1.2)	0.359	2.1 (1.1)	0.036*	2.6 (1.6)	0.203	2.7 (1.4)	0.659
	No	20	2.8 (1.2)		2.7 (1.0)		3.1 (1.5)		2.5 (1.3)	
Nuts allergy	Yes	19	2.6 (0.9)	0.504	2.7 (0.9)	0.019*	3.0 (1.2)	0.267	2.1 (0.9)	0.098
	No	34	2.6 (1.4)		2.1 (1.2)		2.7 (1.8)		2.9 (1.5)	

Statistical tests: Mann-Whitney U test and Kruskal-Wallis test (Bonferroni correction post-hoc)

Mean (SD); p-value;

*Statistical significance.